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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,064	04/27/2000	Ruth Elinor Bauhahn	11738.86893	2481

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EXAMINER
YU, JEANNE C

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	09/560,064	BAUHAHN ET AL.	
	Examiner	Art Unit	
	Jeanne Yu	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *9,19 and 29* is/are allowed.

6)☒ Claim(s) *1-8,10-18,20-28,30-39* is/are rejected.

7)☐ Claim(s) *9,19 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *April 27, 200* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,6,7,8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

The drawings filed on April 27, 2000 are acceptable subject to correction of the informalities indicated on the attached "Notice of Draftperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

- On page 15, line 10, beginning with the new sentence, "The patient programmer 50 comprises..." should be "The INS 5 comprises..."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 recites the limitation "the graphical display screen" in line 2. Claim 23 recites the limitation "the computer instructions" in line 1. Claim 24 recites the limitation "the executed computer instructions" in line 1. Claim 30 recites the limitation "the means for creating, for storing and executing" in line 5. Claim 31 recites the limitation "the user" in line 1. There is insufficient antecedent basis for these limitations.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what "a means, connected to the input medium, for creating at least

one personalized therapy program" refer to within the claim. For example, is it the controller, the memory, or the graphic display? All of these components are connected to the input medium and used to create a personalized therapy program.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,10-18, 20-28 and 30-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Mann USPN 6,052,624 (herein after called '624).

Re claim 1, '624 discloses a method comprised of accessing at least one preset clinician therapy program, or basic operating program (column 8, line 67), stored in the medical device 20 (column 9, line 1). The change of parameters in the basic operating system is read as creating a personalized therapy program from the preset clinician program, or basic operating program (column 9, lines 2-6). The method further comprises storing the personalized therapy program in the memory 67 of the medical device 20 and executing at least one personalized therapy program (column 9, line 19-23), wherein the personalized therapy program is the modified basic operating program.

Re claims 2 and 3, '624 discloses the method wherein the personalized therapy program comprises at least one personalized therapy setting, or stimulation parameter, wherein the personalized therapy setting comprises of at least one of an amplitude, a rate, a pulse width, a pulse frequency, electrode polarities or directional sequence (column 9, line 19).

Re claims 4 and 5, '624 discloses the method wherein the programmer 10 executes directional responsive rules in the software and/or electronics (column 5, lines 31-33). These directional responsive rules, or selection software algorithms (column 12, lines 41-42), are read as both a personalized therapy algorithm and timing algorithm because it allows the patient to automatically adjust the electrode configuration (column 5, lines 33-37), wherein the automatic adjustment would require a timing algorithm and is in itself a personalized therapy algorithm.

Re claim 6, '624 discloses the method wherein the medical device 20 and the patient programmer 10 communicate via telemetry (column 8, lines 29-32) between transmission coil 28 and receiving coil 62.

Re claim 7 and 8, '624 discloses the method wherein the medical device is an implantable or external neurostimulator (column 4, lines 62-67). A medical device 20 having electrodes 24 (Fig 4) to stimulate the senses is read as a neurostimulator.

Re claim 10, '624 discloses a system comprising a medical device 20 comprising a telemetry block, or receiving coil 62 (Fig 2) and memory 67 (Fig 2) with at least one preset clinician therapy program, or basic operating program (column 8, line 67); and a patient programmer 10 (Fig 2) comprising a telemetry block, or transmission coil 28 (Fig 2). The programmer 10 is read as being able to allow the creation of at least one personal therapy program, wherein the creation of a therapy program lies in the steps of defining a group of electrodes with the directional control device 12 and characterizing the stimulation pulses for the group of electrodes with the display screen 16 or keyboard 14 (column 9, lines 36-65). The programmer 10 is read as being able to allow storage of at least one personal therapy program in the memory 67 (Fig 2) of the medical device by transmitting the data commands through coils 28

and 62. The programmer 10 is also being read as able to allow execution of at least one personalized therapy program in the medical device 20 by transmitting the electrode group data and characterization data to the medical device 20 where the medical device 20 acts on the received electrode group data to provide the programmed stimulation currents to the group of electrodes (column 10, lines 9-16).

Re claims 11 and 12, '624 discloses the system wherein the personalized therapy program comprises at least one personalized therapy setting, wherein the personalized therapy setting comprises of at least one of an amplitude, a rate, a pulse width, a pulse frequency, electrode polarities or directional sequence (column 9, line 54).

Re claims 13 and 14, '624 discloses the system wherein the programmer 10 executes directional responsive rules, or a personalized therapy algorithm and timing algorithm, in the software and/or electronics (column 5, lines 31-33). These directional responsive rules, or selection software algorithms (column 12, lines 41-42), are read as both a personalized therapy algorithm and timing algorithm because it allows the patient to automatically adjust the electrode configuration (column 5, lines 33-37), wherein the automatic adjustment would require a timing algorithm and is in itself a personalized therapy algorithm.

Re claim 15, '624 discloses the system wherein the patient uses a graphical display screen 16 (Fig 1A, column 10, lines 23-25) and input medium, or joystick 12 (Fig 4, column 11, line 32), to create and store the personalized therapy programs (column 11, lines 6-48). '624 shows the clinician or patient maneuvering the joystick 12 (column 12, lines 46-47) such that the resulting selected electrodes can be visualized on display 32, or display screen 16 (Fig 4).

Re claim 16, '624 discloses the system wherein the medical device 20 and the programmer 10 communicate via telemetry (column 8, lines 29-32) between transmission coil 28 and receiving coil 62.

Re claims 17 and 18, '624 discloses the system wherein the medical device 20 is an implantable or external neurostimulator (column 4, lines 62-67).

Re claim 20, '624 discloses a programmer 10 comprising an input medium 12 (Fig 1A) and a telemetry block 28 (Fig 3). The stimulator processor circuit 52 (Fig 2) is read as a controller able to create at least one personalized therapy program from the electrode group data and characterization data, received from the directional control device 12 and/or display screen 16 (column 9, lines 38-64), processing the data so that appropriate commands may be sent to the medical device 20 (column 9, line 67 and column 10, lines 1-2), and storing at least one personalized therapy program in the memory 67 (Fig 2) of the medical device 20 (column 9, lines 2-6).

Re claims 21 and 22, '624 discloses the programmer 10 wherein the personalized therapy program comprises at least one personalized therapy setting, wherein the personalized therapy setting comprises of at least one of an amplitude, a rate, a pulse width, a pulse frequency, electrode polarities or directional sequence (column 9, line 54).

Re claims 23 and 24, '624 discloses the programmer 10 executes directional responsive rules, or a personalized therapy algorithm and timing algorithm, in the software, or computer instructions (column 5, lines 31-33). These directional responsive rules, or selection software algorithms (column 12, lines 41-42), are read as both a personalized therapy algorithm and timing algorithm because it allows the patient to automatically adjust the electrode configuration

(column 5, lines 33-37), wherein the automatic adjustment would require a timing algorithm and is in itself a personalized therapy algorithm.

Re claim 25, '624 discloses the programmer 10 wherein the patient uses a graphical display screen 16 (Fig 1A) and input medium, or joystick 12 (Fig 1A), to create and store the personalized therapy programs (column 11, lines 6-48). '624 shows the clinician or patient maneuvering the joystick 12 (column 12, lines 46-47) such that the resulting selected electrodes can be visualized on display 32, or display screen 16 (Fig 4).

Re claim 26, '624 discloses the programmer wherein the medical device 20 and the patient programmer 10 communicate via telemetry (column 8, lines 29-32) between transmission coil 28 and receiving coil 62.

Re claims 27 and 28, '624 discloses the programmer wherein the medical device is an implantable or external neurostimulator (column 4, lines 62-67).

Re claim 30, '624 discloses a patient programmer 10 comprising an input medium 12 (Fig 1A). As described on page 11, line 11, a means for creating a personalized therapy program may be the controller 55. The stimulator processor circuit 52 is read as having the same functional capabilities as the controller 55 because '624 discloses the processor circuit 52 capable of creating a personal therapy program from the electrode group data and characterization data, received from the directional control device 12 and/or display screen 16 (column 9, lines 38-64), processing the data so that appropriate commands may be sent to the medical device 20 (column 9, line 67 and column 10, lines 1-2), and storing at least one personalized therapy program in the memory 67 (Fig 2) of the medical device 20 (column 9, lines 2-6). As described on page 11, lines 12, a communication means, connected to the means

for creating, for storing and executing (i.e. the processor 52) at least one personalized therapy program in a medical device is the telemetry block 65. The transmission coil 28 is read as having the same functional capabilities as the telemetry block 65 because '624 discloses the medical device 20, or receiving coil 62, receiving transmitted data from the programmer 10, or transmission coil 29 (column 8, lines 30-32).

Re claim 31, '624 discloses a programmer 10 comprising an input medium, which may be a display screen 16, directional control device 12, keyboard 14, and/or other I/O devices such as 35, 37, 39 (Fig 4) (column 9, lines 40, 60, 64), for receiving a plurality of personalized therapy settings from a patient (column 12, lines 46-47). Electrode group data (column 9, line 67) and characterization data (column 9, line 58) are read as personal therapy settings, wherein each personalized therapy setting provides settings for a plurality of parameters of a therapy program, or basic operating program (column 8, line 67), selected from the group consisting of an amplitude, a pulse rate, a pulse width, a pulse frequency (column 9, lines 19, 54-55), an electrode polarity and a directional sequence (column 12, lines 51-65). The transmission coil 28 (Fig 2) is read as a telemetry block. The stimulator processor 52 is read as a controller able to create a personalized therapy program for each personalized therapy setting, by processing the characterization and electrode group data received from the patient (column 9, lines 66-67 and column 10, lines 1-2), and cause the personalized therapy programs to be stored in the memory 67 of the medical device 20 (column 9, lines 2-6) via the telemetry block 28 (column 10, lines 9-13), wherein the medical device 20 then acts on the data received by providing the programmed stimulation currents to the group of electrodes selected by the patient through the directional device 12 (column 10, lines 13-16). The operator, or patient, making adjustments in the pulse

width, pulse amplitude, and pulse repetition rate (column 14, lines 45-47) is read as the patient subsequently instructing the medical device 20 via the patient programmer 10 to provide therapy to the patient in accordance with one of the personalized therapy programs, i.e. after the electrode group has been maneuvered to the desired area using the joystick 12.

Re claims 32 and 33, '624 discloses the programmer 10 wherein the controller 52 executes directional responsive rules, or a personalized therapy algorithm and timing algorithm, in the software (column 5, lines 31-33). These directional responsive rules, or selection software algorithms (column 12, lines 41-42), are read as both a personalized therapy algorithm and timing algorithm because it allows the patient to automatically adjust the electrode configuration (column 5, lines 33-37), wherein the automatic adjustment would require a timing algorithm and is in itself a personalized therapy algorithm. '624 clearly discloses the controller 52 processing, or executing, characterization and electrode group data (column 9, lines 66-67) defined from the selection software algorithms (column 12, lines 40-41) so that the appropriate commands may be sent to the medical device 20 (column 10, lines 1-2).

Re claim 34, '624 discloses the programmer wherein the input medium 16 is a graphical screen interface, or touch-sensitive screen (column 9, lines 60-63 and column 11, line 34-37), to create the personalized therapy program.

Re claims 35 and 36, '624 discloses the programmer wherein the telemetry block 28 is capable of communicating a medical device 20 (column 10, lines 8-13), wherein the medical device 20 is an implantable or external neurostimulator (column 4, lines 62-67).

Re claim 37, '624 discloses stimulation parameters, or the personalized therapy program, based on user activity, or patient's activity (column 2, lines 13-14). Although '624 does not

specifically mention this factor in the preferred embodiment, a reference is not limited to its preferred embodiment, but must be evaluated for all of its teachings, including teachings of non-preferred embodiments. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann USPN 6,052,624 in view of Wernicke et al. (USPN 5,231,988).

Mann discloses a programmer 10 comprising a controller 52 that is capable of programming an implanted device 20 to provide therapy to a patient in accordance with a personalized therapy program. Mann does not disclose expressly that the personalized therapy program is based on time of day or associated with a particular time of day. Wernicke et al. discloses a therapy program to activate a neurostimulator based on a particular time of day, i.e. after meal periods (column 4, lines 38-43). Mann and Wernicke et al. are analogous art because they are from the same field of endeavor, i.e. programming stimulation parameters of a medical device. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the therapy program of Mann with the therapy program based on time of day or associated with a time of day of Wernicke et al. The motivation for doing so would have been to secrete insulin in a diabetic patient after an increase in glucose level due to food consumption

(Wernicke et al. column 8, lines 4-23). Therefore, it would have been obvious to combine Mann with Wernicke et al. to obtain the invention as specified in claims 38 and 39.

Allowable Subject Matter

Claims 9, 19 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: None of the prior art of record disclosed a method or apparatus of an external programmer storing a therapy program comprising at least one personalized therapy setting in a medical device, wherein the medical device is selected from a group consisting of a pacemaker, a defibrillator, a cochlear implant, an implantable diagnostic device, and an implantable pump.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patent is cited to further show the state of the art with respect to an implantable and/or external stimulator and patient programmer:

USPN 5,443,486 to Hrdlicka et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeanne Yu whose telephone number is 703-305-7569. The examiner can normally be reached on Monday-Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-3139 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

jcy
November 1, 2002

MARK BOCKELMAN
PRIMARY EXAMINER